Cl. 21, line 1, delete "A", insert --The--.

line 1, delete "15", insert --20--.

Please cancel claims 23, 25, 27 and 29-35.

Please add the following claims.

36. The method of claim 15, wherein the oncogene expressed by the recombinant pox virus is derived from a homologous oncogene to the human cellular oncogene.

37. The method of claim 36, wherein the homologous oncogene is of rat origin.

Remarks:

Applicants have amended the claims to more explicitly claim their invention. These amendments are supported by the specification, particularly the examples. As such, they do not constitute new matter and their entry is respectfully requested.

Claims 15-22 were rejected pursuant to 35 U.S.C. §101 and §112 first paragraph.

It is the Examiner's contention that there is no teaching in the specification that the present invention would work, thus, the invention described by the claims allegedly lack utility and because utility has not been proven, they also lack enablement.

Applicants respectfully submit that this rejection should be withdrawn for the following reason.

As explained in the specification at page 36, line 15 through 21, the data demonstrates that immunization using a recombinant vaccinia virus containing a heterologous DNA segment encoding a single well-defined antigen, the rat neu oncogene can confer protection against tumor cells expressing that antigen. Admittedly, the data also discloses that the vaccinia virus recombinant was not able to result in tumor rejection as a result of antibody expression in a syngeneic system, namely using the rat neu gene product in rats having tumors expressing the rat neu gene. However, as amended, it is clear that claim 15 and particularly claims 36 and 37 are not addressed to just a syngeneic system. Rather, the skilled artisan can use a recombinant pox virus expressing a homologous oncogene to the human cellular oncogene being expressed by the tumor.

The present invention is premised on the recognition that the

normal human immune system does not very efficiently deal with human tumor cells in mounting an immunological response thereto. Applicants recognize that a virus, such as vaccinia, could be an effective way of stimulating a broadly based immunological response and that by creating a recombinant vaccinia virus expressing such an antigen, one could get a better immune response and thus method of immunologically treating humans afflicted with tumors. Applicant's test with mice established that this premise is correct. As shown by applicants, using a recombinant pox virus, they were able to stimulate the immune system to get a stronger immunological response to the tumor. Thus, applicants have shown that the immune system can in fact, regulate or modulate the tumor. Having taught this, applicants have established utility and enablement. Although the experiments using the same recombinant virus did not work in the rats tested, the skilled artisan would recognize that there are ways to, in essence, prime the immune system to generate an immune response. For example, using a method of inoculating, which has a first shot and then a booster shot, screening for a particular adjuvant that enhances the effect or incorporating other immunostimulants such as lymphokines. This is information which the skilled artisan would readily know. Unfortunately, because of commercial constraints, applicants have been unable to carry out further tests with this system. However, applicants respectfully submit that their data does establish the critical

point, which is that by use of their vector an immune system can modulate tumor expressing an oncogene. Thus, a tumor caused by an oncogene can be modulated by using a recombinant virus which expresses such oncogene.

Accordingly, applicants respectfully submit that the claims comply with 35 U.S.C. §101 and §112.

Claims 15-22 were rejected pursuant to 35 U.S.C. §103 as being unpatentable over Lathe, et al. in view of Padhy, et al., and further in view of Yamamoto, et al.

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The present invention is directed to immunizing an individual against a specific type of tumor, namely one which expresses an oncogene. Lathe, et al. in no way discloses or suggests a method for immunizing against such a tumor. Rather, Lathe is directed to a method of immunizing a tumor-bearing animal with a vaccinia virus expressing antigens of polyomavirus. The Examiner has recognized this difference and relies on Padhy, et al. and Yamamoto, et al. to fill this gap. However, there is nothing in these two references that teach or suggest that if one was to

substitute an oncogene for the polyomavirus antigen of Lathe and use such a recombinant against a tumor expressing the oncogene, one would obtain immunization. Indeed, this is precisely the point the Examiner has made in her rejection of the claims pursuant to 35 U.S.C. §101/112. In this case, the prior art offers no suggestion, explicit or implicit that the substitution between the claimed invention in the prior art would provide a reasonable expectation of success. Accordingly, this rejection of the claims should be withdrawn. See, e.g. In Re Vaeck, 946 F.2d 488, 493-95 (Fed. Cir. 1991).

Thus, applicants respectfully request withdrawal of this rejection.

Early and favorable action is requested.

Respectfully submitted,

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